



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/530,746	11/16/2000	Christoph Kessler	1803-277-999	6382
7590 07/14/2004 Richard H. Zaitlen, Esq. PILLSBURY WINTHROP LLP 725 South Figueroa Street Suite 2800			EXAMINER	
			STRZELECKA, TERESA E	
			ART UNIT	PAPER NUMBER
			1637	
Los Angeles, C	CA 90017-5406		DATE MAILED: 07/14/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	٠
*	
- 1	٠,
, p	
~	•
	١
•	2
1.4	,

Applicant(s) Application No. KESSLER ET AL. 09/530,746 Office Action Summary Examiner Art Unit 1637 Teresa E Strzelecka -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure Any re	e to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). The ply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any depend patent term adjustment. See 37 CFR 1.704(b).				
Status					
1)🖂	Responsive to communication(s) filed on <u>19 May 2004</u> .				
2a)⊠	This action is FINAL . 2b) ☐ This action is non-final.				
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
•	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Dispositio	on of Claims				
4)🛛	Claim(s) <u>1-15</u> is/are pending in the application.				
4	a) Of the above claim(s) is/are withdrawn from consideration.				
5)□ ←	Claim(s) is/are allowed.				
6)🖂	6)⊠ Claim(s) <u>1-15</u> is/are rejected.				
7)	Claim(s) is/are objected to.				
8)[Claim(s) are subject to restriction and/or election requirement.				
Application	on Papers				
9)∭ ⊺	The specification is objected to by the Examiner.				
10)□ 7	Γhe drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11)[] 7	The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority u	nder 35 U.S.C. § 119				
12) 🗌 A	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a)[☐ All b) ☐ Some * c) ☐ None of:				
	1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority documents have been received in Application No				
	3. Copies of the certified copies of the priority documents have been received in this National Stage				
	application from the International Bureau (PCT Rule 17.2(a)).				
* S	ee the attached detailed Office action for a list of the certified copies not received.				
Attachment	_				
	e of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date				
	partion Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152)				

Paper No(s)/Mail Date 5/19/04.

6) Other: _

Art Unit: 1637

DETAILED ACTION

1. This office action is in response to an amendment filed May 19, 2004. Claims 1-15 were previously pending. Applicants amended claims 1 and 15. Claims 1-15 are pending and will be examined.

2. Applicants' arguments overcame the rejection of claim 15 under 35 U.S.C. 112, second paragraph. All other rejections are maintained for reasons given in the "Response to Arguments" section below.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 19, 2004 was filed after the mailing date of the first office action on December 15, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

- 4. Applicant's arguments filed May 19, 2004 have been fully considered but they are not persuasive.
- A) Regarding the rejection of claims 1-3, 5-7, 10 and 14 under 35 U.S.C. 102 (b) as anticipated by Birkenmeyer et al., Applicants argue that:
- a) Primers of Birkenmeyer et al. do not produce the required amplicons which are shorter than 100 nucleotides. Specifically, Applicants cite primer pairs 4, 6 and 8 which failed to give amplification products. Applicants provide arguments for primer pair 7, which was not cited in the office action.
- b) Primer pairs 5 and 9 resulted in non-specific amplification, as shown in Fig. 2, where probe of SEQ ID NO: 8 hybridizes to two bands in lanes 5 and 9.

Art Unit: 1637

Regarding a), the office action cited primer pairs 5 and 9, which do produce amplification fragments less than 100 nucleotides long, i.e., 57 and 44 bp, respectively, therefore this limitation is anticipated by Birkenmeyer et al. As the previous office action did not discuss primer pair 7, Applicants' arguments are moot.

Regarding b), Applicants did not define the term "specific". Therefore, the term is interpreted as meaning that a probe will hybridize to a target nucleic acid when there are enough nucleotides which are complementary between the probe and the target under given hybridization conditions. Therefore, presence of two amplification products detected by a probe is still a "specific" detection. The fragments on top of lanes 5 and 9 of the gel in Fig. 2 are the usual artifacts of aggregated material which do not enter the gel or enter it at the very top. Therefore, both high-molecular weight bands in lanes 5 and 9 are not non-specific amplification products. As to the additional band in lane 5, it might be due to primer dimmers, for example, which would be detected with a probe. In any case, as explained above, even if this band represents a different amplification product produced by primer pair 5, the detection is still specific.

In summary, Birkenmeyer et al. do anticipate all of the limitations of claims 1-3, 5-7, 10 and 14, and therefore the rejection is maintained.

B) Regarding the rejection of claim 8 under 35 U.S.C. 103 (a) over Birkenmeyer et al. and Livak et al., rejection of claim 9 under 35 U.S.C. 103 (a) over Birkenmeyer et al. and Wittwer, rejection of claim 15 under 35 U.S.C. 103 (a) over Birkenmeyer et al. and Koster and rejection of claims 4 and 11-13 under 35 U.S.C. 103 (a) over Birkenmeyer et al. and Greisen et al., Applicants argue that since Birkenmeyer et al. do not anticipate claim 1, these rejections are improper.

The arguments regarding claim 1 and its anticipation by Birkenmeyer et al. have been provided above.

Art Unit: 1637

The rejections are maintained.

C) Regarding the provisional obviousness-type double-patenting rejection of claims 1, 4, 5, 8 and 11-14 over claims 1 and 3-9 of the co-pending application No. 09/530,747, Appplicants state that they will consider providing a terminal disclaimer if one of the applications is allowed.

However, the terminal disclaimer was not provided, therefore the rejection is maintained.

A provisional obviousness-type double-patenting rejection was made for claims 1-15 over claims 1-15 of the co-pending application No. 09/530,929. Applicants did not address this rejection in the response, therefore it is maintained.

Claim interpretation

- 5. The term "specific detection" and "specific hybrid" have not been defined by Applicants.

 Therefore the term "specific hybrid" is interpreted as formation of a hybridization product between a probe and a target nucleic acid, and "specific detection" as detection of such a hybrid.
- 6. The terms "non-specific primer" or "non-specific probe" are interpreted as primers and probes which are used to amplify and detect several different targets simultaneously.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-3, 5-7, 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Birkenmeyer et al. (U.S. Patent No. 5,453,355).

Regarding claim 1, Birkenmeyer et al. teach a method for specific detection of a nucleic acid comprising the steps:

Art Unit: 1637

(a)- producing a plurality of amplificates of a section of the nucleic acid with the aid of two primers, one of which binds to a binding sequence A', which is complementary to a seguence A of one strand of the nucleic acid and the other binds to a binding sequence which is located in the 3' direction from A and does not overlap A (Birkenmeyer et al. teach amplification of Neisseria gonorrhoeae by polymerase chain reaction (= producing a plurality of amplificates), using primers pairs in which one of the primers binds to a sequence on a (+) strand of the N. gonorrhoeae sequence fragment extending from bp 827-972, and a second primer which binds to a sequence 3' from the first primer and is complementary to the (-) strand (Fig. 1; Table 1).),

- (b)- contacting the amplificates with a probe having a binding sequence D which binds either to a sequence B or to the complement thereof, wherein the sequence B is located between the sequences A and C (Birkenmeyer et al. teach contacting the amplified fragments with a probe having a binding sequence on the (+) strand and located between the primer sequences (Table 1; col. 6, lines 31-43).), and
- (c)- detecting the formation of a specific hybrid of the amplificate and probe (Birkenmeyer et al. teach detection of the complex between the amplificate and the probe by gel electrophoresis (col. 9, lines 12-34; Fig. 2),

wherein the sequence located between the sequences A and C contains no nucleotides or less than 3 nucleotides that do not belong to the sequence region E formed from the binding sequence D of the probe and the sequence of the amplificate bound thereto and the amplificates are shorter than 100 nucleotides (Birkenmeyer et al. teach a probe with SEQ ID NO: 8, which spans bp 894-936 of the N. gonorrhoeae pil E gene (Table 1). The primer pairs 5 (SEQ ID NO: 4 and 5) and 6 (SEQ ID NO: 4 and 7) amplify DNA fragments of 57 and 51 bp, respectively, with the probe spanning the

Art Unit: 1637

whole first primer and extending 2 bp into the second primer. Similarly, primer pairs 8 (SEQ ID NO: 6 and 5) and 9 (SEQ ID NO: 6 and 7) amplify DNA fragments of 50 and 44 bp, respectively, with the probe spanning the whole first primer and extending 2 bp into the second primer.

Therefore Birkenmeyer et al. teach the limitation of no nucleotides between primer sequences which do not belong to the complex between the amplificate and the probe and the limitation of an amplificate shorter than 100 bp; see Fig. 2).

Regarding claim 2, Birkenmeyer et al. teach the probe overlapping with primer sequences of primers with SEQ ID NO: 4, 5, 6 and 7 (Table 1; see explanation for claim 1).

Regarding claim 3, Birkenmeyer et al. teach a primer in which the 5' end (=non-extendible part) contains nucleotides which are not complementary to the target sequence, therefore they do not hybridize to the target sequence (col. 5, lines 45-48).

Regarding claim 5, Birkenmeyer et al. teach amplificates which are 57, 51, 50 or 44 bp in length (Table 1; Fig. 2), therefore do not exceed 74 bp.

Regarding claims 6 and 7, Birkenmeyer et al. teach primers which are immobilizably-labeled with a hapten, which is then used to capture the amplificate (col. 7, lines 25-40), detectably-labeled probe (col. 6, lines 39-45) and detectably-labeled primers (col. 7, lines 19-21). Birkenmeyer et al. teach that the probe may be immobilized and the hapten detected or vice versa (col. 7, lines 44-48).

Regarding claim 10, Birkenmeyer et al. teach detection of the amplificate by gel electrophoresis (= physical means) and autoradiography (= spectroscopic method) (col. 9, lines 12-34).

Regarding claim 14, Birkenmeyer et al. teach nucleotides complementary to A, G, C and T in the amplication reaction (col. 8, lines 63-65).

Art Unit: 1637

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birkenmeyer et al. and Livak et al. (U. S. Patent No. 5,538,848; cited in the IDS and in the previous office action).
 - A) Claim 8 is drawn to a probe labeled with a fluorescence quencher and a fluorescent dye.
- B) Teachings of Birkenmeyer et al. are described above. Birkenmeyer et al. teach labeled probes, but do not teach a probe labeled with a fluorescence quencher and a fluorescent dye.
- C) Livak et al. teach a probe labeled with a reporter molecule (= fluorescent dye) and a quencher, the probe being used for monitoring of the progress of amplification reaction (Abstract; Figure 1; col. 3, lines 29-56; col. 5, lines 38-58).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the reporter-quencher labeled probe of Livak et al. in the detection method of Birkenmeyer et al. The motivation to do so, provided by Livak et al., would have been that real-time quantitation of nucleic acid amplification was achieved using such probe, and real-time monitoring of amplification prevented cross-contamination of samples, especially important in diagnostic applications (col. 1, lines 22-52; col. 3, lines 8-12).

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birkenmeyer et al. and Wittwer (U. S. Patent No. 6,245,514 B1; cited in the previous office action).

Art Unit: 1637

A) Claim 9 is drawn to one of the primers labeled with a first energy transfer component and a probe labeled with a second energy transfer component which is different from the first energy transfer component.

- B) Teachings of Birkenmeyer et al. are described above. Birkenmeyer et al. teach labeled primers and probes, but do not teach one of the primers labeled with a first energy transfer component and a probe labeled with a second energy transfer component which is different from the first energy transfer component.
- C) Wittwer teaches fluorescence energy transfer pairs for detecting the presence of target analyte. Wittwer teaches detection of PCR products by resonance energy transfer between one labeled primer and one labeled probe which hybridizes between the PCR primers. Exemplary energy transfer pair can comprise fluorescein as a donor and Cy5 or Cy5.5 as the acceptor (col. 3, lines 66, 67; col. 4, lines 1-3; col. 5, lines 63-67; col. 6, lines 1-13, 54, 55; col. 7, lines 31-52; col. 31, lines 35-67; col. 32, lines 1-63).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the donor-acceptor energy transfer between a primer and a probe of Wittwer in the detection method of Birkenmeyer et al. The motivation to do so, provided by Wittwer, would have been that using labeled probe and primer provided "a superior monitor of product accumulation for quantitation" and resulted in more precise measurement of fluorescence intensity than other methods (col. 32, lines 6-18 and 59-63).

- 12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birkenmeyer et al. and Koster (WO 96/29431, cited in the IDS and in the previous office action).
 - A) Claim 15 is drawn to the detection of amplificates by mass spectroscopy.

Art Unit: 1637

B) Teachings of Birkenmeyer et al. are described above. Birkenmeyer et al. do not teach detection of amplificates by mass spectroscopy.

C) Koster teaches detection of nucleic acids by mass spectrometry. Koster teaches detection of an amplified target nucleic acid (= amplificate) by immobilization of the target nucleic acid on a solid support and detection of the target by mass spectrometry. Immobilization of the target can be achieved by hybridizing the target with a capture probe which has been immobilized on solid support (page 4, lines 15-38; page 5, lines 1-11; Figure 1A; Figure 4; page 15, lines 34-39; page 16, lines 1-28). Mass spectrometry was used to detect a 67 bp amplification product from hepatitis B virus (HBV) (page 27, lines 24-39; page 28-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used mass spectrometry detection of PCR products of Koster in the detection method of Birkenmeyer et el. The motivation to do so, provided by Koster, would have been that mass spectrometry provided high detection sensitivity and accuracy of mass, i.e., molecular weight, determination (page 2, lines 33-37).

- 13. Claims 4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birkenmeyer et al. and Greisen et al. (J. Clin. Microbiol., vol. 32, pp. 335-351, 1994).
- A) Teachings of Birkenmeyer et al. are described above. Birkenmeyer et al. do not teach amplification of a nucleic acid target with primers or probes which are not specific for the nucleic acid.
- B) Greisen et al. teach amplification of bacteria causing meningitis using universal (= non-specific) primers and probes, with which a number of bacterial species found in CSF were amplified and detected. The primers were DG74, RW01 and RDR080 (Table 3). These primers amplified 18 species of bacteria found in CSF (page 343, first paragraph; Table 1). In addition, universal

Art Unit: 1637

probesfor different bacterial species were designed, with probe COR28 designed to detect N. meningitis serotypes and N. gonorrhoeae (page 343, sixth paragraph; Table 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the non-specific primers and probes of Greisen et al. in the method of Birkenmeyer et al. The motivation to do so, provided by Greisen et al., would have been that amplification with non-specific primers and detection with non-specific probes provided a very sensitive way of detecting pathogenic bacteria in CSF, as 10 copies of E. coli DNA, corresponding to three E. coli cells, were detected (page 349, fourth paragraph). As stated by Greisen et al., "... A clinical PCR assay based on these primers may have sufficient sensitivity to allow direct detection of bacteria in CSF without an intermediate culturing step..." (page 349, fourth paragraph), and "... The PCR primers and panel of probes described here can form the basis of a more rapid and sensitive means of detecting bacteria in clinical samples." (page 350, last paragraph).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 4, 5, 8 and 11-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-9 of copending Application No. 09/530,747.

Art Unit: 1637

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 is generic to all that is recited in claim 1 of the 09/530,747 application. That is, claim 1 of the 09/530,747 application falls entirely within the scope of claim 1 of the instant application, or, in other words, claims 1 is anticipated by claim 1 of the 09/530,747 application.

Specifically, claim 1 of the instant application is drawn to a method of detection of nucleic acids comprising the steps:

- (a)- producing a plurality of amplificates of a section of the nucleic acid with the aid of two primers, one of which binds to a binding sequence A', which is complementary to a seguence A of one strand of the nucleic acid and the other binds to a binding sequence which is located in the 3' direction from A and does not overlap A,
- (b)- contacting the amplificates with a probe having a binding sequence D which binds either to a sequence B or to the complement thereof, wherein the sequence B is located between the sequences A and C, and
- (c)- detecting the formation of a hybrid of the amplificate and probe,

wherein the sequence located between the sequences A and C contains no nucleotides or less than 3 nucleotides that do not belong to the sequence region E formed from the binding sequence D

Art Unit: 1637

of the probe and the sequence of the amplificate bound thereto and the amplificates are shorter than 100 nucleotides.

Claim 1 of the 09/530,747 application is drawn to the method in which the probe has a reporter group and a quencher group, the polymerase has a 5' nuclease activity and the amplificates have fewer than 75 nucleotides, which makes this claim a species of a genus defined by claim 1 of the instant application. The dependent claims 3-9 of the 09/530,747 application are identical to claims 4, 5, 8, and 11-14 of the instant application, therefore they anticipate these dependent claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/530,929.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 is generic to all that is recited in claim 1 of the 09/530,929 application. That is, claim 1 of the 09/530,929 application falls entirely within the scope of claim 1 of the instant application, or, in other words, claims 1 is anticipated by claim 1 of the 09/530,929 application.

Art Unit: 1637

Specifically, claim 1 of the instant application is drawn to a method of detection of nucleic acids comprising the steps:

- (a)- producing a plurality of amplificates of a section of the nucleic acid with the aid of two primers, one of which binds to a binding sequence A', which is complementary to a seguence A of one strand of the nucleic acid and the other binds to a binding sequence which is located in the 3' direction from A and does not overlap A,
- (b)- contacting the amplificates with a probe having a binding sequence D which binds either to a sequence B or to the complement thereof, wherein the sequence B is located between the sequences A and C, and
- (c)- detecting the formation of a hybrid of the amplificate and probe,

wherein the sequence located between the sequences A and C contains no nucleotides or less than 3 nucleotides that do not belong to the sequence region E formed from the binding sequence D of the probe and the sequence of the amplificate bound thereto and the amplificates are shorter than 100 nucleotides.

Claim 1 of the 09/530,929 application is drawn to the method in which the sequence between the binding sequences A and C contains no nucleotides that do not belong to the sequence region E of the amplificate that is bound by binding sequence D of the probe, which makes this claim a species of a genus defined by claim 1 of the instant application. The dependent claims 2-15 of the 09/530,929 application are identical to claims 2-15 of the instant application, therefore they anticipate these dependent claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. No claims are allowed.

Art Unit: 1637

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS July 7, 2004

JEFFREY FREDMAN PRIMARY EXAMINER